**510(k) Summary**
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OCT 23 2009

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**Official Contact:** Izhak Fabian - CEO

**Proprietary or Trade Name:** ClearPath

**Common/Usual Name:** External uterine monitor

**Classification Name/Code:** FDF - colonoscope and accessories, flexible/rigid
CFR 876.1500

**Device:** ClearPath

**Predicate Devices:** K032688 – Sightline - Colonsight 510B
K031773 - Bryne Medical - EndoGator
K000948 Olympus (KeyMed) - OFP-1 endoscopic flushing pump

**Device Description:**
The ClearPath's main purpose is to improve procedure reliability and decrease colonoscopy procedures cancellation rate by enabling intra-procedural cleaning of a poorly prepared colon.

The ClearPath utilizes a suction / irrigation head for the purpose of irrigating or cleaning the colon and enabling the rapid evacuation of large amounts of water and feces.

The ClearPath is composed of two major units:

- The disposable Irrigator and
- the reusable Control cabinet.

The disposable Irrigator is attached to a standard colonoscope by means of silicon bands and does not hinder colonoscope functionality nor affects the procedure sequence in any way.

The Control cabinet supplies the water flow and vacuum control using a peristaltic pump. The standard medical facility vacuum system is the vacuum source.

**Indications for Use:**
The ClearPath is intended to connect to standard colonoscopes to help facilitate intra-procedural cleaning of a poorly prepared colon by irrigating or cleaning the colon and evacuating the irrigation fluid (water) and feces.

It is for use only by trained medical personnel located in hospitals, clinics, and doctors' offices.

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**Patient Population:**
Individuals undergoing procedures where a colonoscope is used.

**Environment of Use:**
Hospitals, clinics, and doctors' offices.

**Summary of substantial equivalence:**

We have performed testing to demonstrate that the operating performance specifications of the ClearPath is equivalent to the predicates for flow rate, irrigation and vacuum pressures.

| | Proposed ClearPath (ACE-1000) | Olympus (KeyMed) OFP-1 endoscopic flushing pump |
|---|---|---|
| **510(k) number** | | K000948 |
| **Air / Water pressure specifications** | Up to 30 Psi | 52 Psi |
| **Flow rate** | Up to 300 ml/min | Up to 300 ml/min |
| **Suction specifications** | Standard wall suction Approximately 0.5 Bar | Standard wall suction Approximately 0.5 Bar |

In addition we have preformed testing under the following standards:

- IEC 60601
- IEC 60601-1
- IEC 60601-2-18

The ClearPath is viewed as substantially equivalent to the predicate devices because:

**Indications –**

- Identical to predicate – K032688 – Sightline Colonsight 510B

**Technology –**

- Similar technology used –
  - K032688 – Sightline Colonsight 510B
  - K031773 - Bryne Medical EndoGator

**Environment of Use –**

- Identical to predicate – K032688 – Sightline Colonsight 510B

**Performance specifications –**

- Irrigation pressures, flow rate and suction pressures are equal or less than the predicates – K000948 Olympus (KeyMed) OFP-1 endoscopic flushing pump

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

OCT 23 2009

EasyGlide Ltd.
c/o Mr. Paul E. Dryden
President
Regulatory Consultant
ProMedic, Inc.
24301 Woodsage Drive
BONITA SPRINGS FL 34134-2958

Re: K091305
Trade/Device Name: ClearPath
Regulation Number: 21 CFR §876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: FDF
Dated: October 12, 2009
Received: October 14, 2009

Dear Mr. Dryden:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

K091305
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## Indications for Use Statement



**510(k) Number:** K091305 (To be assigned)

**Device Name:** ClearPath

**Indications for Use:**

The ClearPath is intended to connect to standard colonoscopes to help facilitate intra-procedural cleaning of a poorly prepared colon by irrigating or cleaning the colon and evacuating the irrigation fluid (water) and feces.

It is for use only by trained medical personnel located in hospitals, clinics, and doctors' offices.

**Prescription Use XX** (Part 21 CFR 801 Subpart D) **or** **Over-the-counter use __** (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K091305